EXHIBIT 6

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH)
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	

EXHIBIT 6

SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S DISPUTED LAW FOR AFFIRMATIVE CASE

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In accordance with Local Rule 16.3(c) of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Sarepta Therapeutics, Inc. ("Sarepta") and the University of Western Australia ("UWA") (collectively, "Counter-Plaintiffs") provide a statement of the issues of law which Counter-Plaintiffs contend remain to be litigated. By submitting this statement, Counter-Plaintiffs are in no way waiving their rights to amend or supplement their submission after they consider the submissions of Nippon Shinyaku Co., Ltd. ("NS Japan") and NS Pharma, Inc. ("NS Pharma") (collectively, "Counter-Defendants"), whether made as part of this Pretrial Order or otherwise made apparent in pretrial proceedings, the trial itself, or post-trial briefing.

To the extent the statement below contains issues of fact, those issues are incorporated into Counter-Plaintiffs' Disputed Facts for Affirmative Case in Exhibit 4. To the extent Counter-Plaintiffs' Disputed Facts for Affirmative Case contain issues of law, those issues are incorporated herein by reference.

I. INFRINGEMENT OF THE WILTON PATENTS[1]

A. Infringement Generally

Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants infringed, and continue to infringe, any of claims 1 and 2 of U.S. Patent No. 9,994,851 ("the '851 Patent"), claims 1 and 2 of U.S. Patent No. 10,227,590 ("the '590 Patent"), and claims 1 and 2 of U.S. Patent No. 10,266,827 ("the '827 Patent") ("Asserted Claims of the Wilton Patents").

Legal Authority:

[1] The Wilton Patents refer to U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827.

1. "Patent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence." *Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011).

2. "An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device [or process] accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (internal citation omitted). Literal infringement requires that "each limitation in the asserted claim be found present in the accused device or process." *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1582 (Fed. Cir. 1995).

B. Direct Infringement

Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants directly infringed, and continue to directly infringe, any of claims 1 and 2 of the '851 Patent and claims 1 and 2 of the '590 Patent under 35 U.S.C. § 271(a).

Legal Authority:

3. Under 35 U.S.C. § 271(a), "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."

4. In determining whether a "sale" (or an offer for "sale") has occurred in the United States under 35 U.S.C. § 271(a), "the ordinary meaning of a sale includes the concept of a transfer of title or property." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 831 F.3d 1369, 1377-78 (Fed. Cir. 2016). "A 'sale' is not limited to the transfer of tangible property; a sale may also be the agreement by which such a transfer takes place." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk*

Contractors USA, Inc., 617 F.3d 1296, 1311 (Fed. Cir. 2010); *see also id.* ("a contract can constitute a sale to trigger infringement liability").

5. An "offer to sale" in the United States under 35 U.S.C. § 271(a) has been similarly defined "according to the norms of traditional contractual analysis." *See Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1254-55 (Fed. Cir. 2000).

6. "Even if an infringing product is manufactured outside of the United States, a person infringes if he imports the product, or uses, offers to sell, or sells it within the United States." *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1380 (Fed. Cir. 2009); *In re N. Pigment Co.*, 71 F.2d 447, 456 (C.C.P.A. 1934) ("It has long been settled that articles patented in the United States cannot be manufactured abroad, imported, and sold in violation of the rights of the patentee.").

7. "Under federal patent law, when infringement results from the participation and combined or successive action of several parties, those parties are joint infringers, and are jointly liable." *FMC Corp. v. Up-Right, Inc.*, 816 F. Supp. 1455, 1461 (N.D. Cal. 1993), *aff'd* 21 F.3d 1073 (Fed. Cir. 1994); *see also Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1364 (Fed. Cir. 2001) ("other courts, including the Supreme Court, have held that parties that make and sell an infringing device are joint tort-feasors with parties that purchase an infringing device for use or resale").

C. Induced Infringement

Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants induced infringement and continue to induce infringement any of the Asserted Claims of the Wilton Patents under 35 U.S.C. § 271(b).

Legal Authority:

8. Under 35 U.S.C. 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer."

9. To prove induced infringement, the patentee must show that: (1) a third party directly infringed the asserted patent; (2) the defendant induced those infringing acts; and (3) the defendant knew the acts it induced constituted infringement. *See Minn. Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002).

10. "[W]hile proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." *Sanofi v. Watson Laby's, Inc.*, 875 F.3d 636, 644 (Fed. Cir. 2017) (quoting *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part)). For example, the intent can be shown with the label accompanying the marketing of a drug that "encourage[s], recommend[s], or promote[s] infringement." *See id.* (quoting *Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)). The intent can also be inferred from press releases, marketing materials, and product catalogs. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1337-38 (Fed. Cir. 2021).

11. Liability for inducing infringement attaches when "the defendant knew of the patent and that the induced acts constitute patent infringement." *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639 (2015) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011)). The defendant's belief regarding patent validity is not a defense to a claim of induced infringement. *Id.* at 642. A defendant who is willfully blind cannot avoid liability of induced infringement. *Global-Tech*, 563 U.S. at 766-70.

D. Contributory Infringement

Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants contributorily infringed, and continue to contributorily infringe, any of the Asserted Claims of the Wilton Patents under 35 U.S.C. § 271(c).

Legal Authority:

12. Under 35 U.S.C. § 271(c), "[w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer."

13. To prove contributory infringement, the patentee must show: (1) the defendant offers to sell or sells within the United States or imports into the United States a component of a patented composition or a material for use in practicing a patented process; (2) the component or material constitutes a material part of the invention; (3) the defendant knew that the component or material is especially made or especially adapted for use in an infringement of such patent; (4) the component or material is not a staple article or commodity of commerce suitable for substantial noninfringing use; and (5) the component or material was used by a third party to practice the claimed invention. *Id.*; *see also Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1348 (Fed. Cir. 2015) ("For contributory infringement, as for inducement, direct infringement is necessary and will typically take place later than the accused indirect infringer's act.").

14. A drug product is not a "staple article of commerce suitable for substantial noninfringement use" under 35 U.S.C. § 271(c) when "the only authorized use . . . is the patented use." *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 927 (Fed. Cir. 2011); *see also id.* at 926 ("We have long held that the sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent, and usually is also contributory infringement.").

II. DAMAGES

A. Lost Profits

Whether Counter-Plaintiffs are entitled to damages in the form of lost profits under 35 U.S.C. § 284 to compensate for Counter-Defendants' infringement of the Asserted Claims of the Wilton Patents, and if so, the amount.

Legal Authority:

15. The assessment of damages is a question of fact, and is decided by the jury when trial is to a jury. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1578 (Fed. Cir. 1992).

16. The plaintiff must prove the amount of its damages by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Laby's Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991).

17. Pursuant to 35 U.S.C. § 284, a plaintiff should receive "full compensation" for any damages it suffered as a result of a defendant's infringement. *See Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654 (1983). "Full compensation includes any foreseeable lost profits the [plaintiff] can prove." *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). "Being responsible for lost sales of a competitive product is surely foreseeable; such losses constitute full compensation set forth by Congress, as interpreted by the Supreme Court, while staying well within the traditional meaning of proximate cause." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1546 (Fed. Cir. 1995). "[C]ourts have given [plaintiffs] significant latitude to prove and recover lost profits for a wide variety of foreseeable economic effects of the infringement." *Grain Processing*, 185 F.3d at 1350.

18. An award of lost profits must be based on the profits the plaintiff lost. "[U]nlike copyright and trademark infringements, patent infringement carries no remedy of an accounting

for an infringer's profits. That remedy was eliminated by the 1946 amendment of the patent statute and, thus, the infringer's profits are not, as such, a measure of the [plaintiff]'s damages." *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 673 (Fed. Cir. 1988).

19. In demonstrating lost profits, a plaintiff asserting patent infringement must show a reasonable probability that "but for" the infringement, plaintiff would have made the defendant's infringing sales. *See Grain Processing*, 185 F.3d at 1349. The "but for" inquiry requires a construction of a hypothetical market as it would have developed absent infringement to determine what the plaintiff would have made. *Id*. at 1350. The *Panduit* case sets forth an accepted framework for proving entitlement to lost profits. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978). Under the *Panduit* framework, the plaintiff seeking lost profits must establish (1) demand for the patented product, (2) an absence of acceptable non-infringing substitutes, (3) manufacturing and marketing capacity to exploit the demand, and (4) the amount of profit it would have made. *Id*. Under a market share approach for calculating lost profits, "[t]he question then becomes whether an established market share combined with the other *Panduit* factors is sufficient to show [the plaintiff's] loss to a reasonable probability." *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989).

B. Reasonable Royalty

Whether Counter-Plaintiffs are entitled to damages in the form of a reasonable royalty under 35 U.S.C. § 284 to compensate for Counter-Defendants' infringement of the Asserted Claims of the Wilton Patents, and if so, the amount.

Legal Authority:

20. Under 35 U.S.C. § 284, upon a finding of infringement, "the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer . . . ."

21. Thus, a reasonable royalty is "merely the floor below which damages shall not fall." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009) (quoting *Bandag, Inc. v. Gerrard Tire Co.*, 704 F.2d 1578, 1583 (Fed. Cir. 1983)). The plaintiff bears the burden of proving damages. *Id.*

22. Reasonable royalty damages may be determined using the "hypothetical negotiation" method, which "attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began." *Lucent Techs.*, 580 F.3d at 1324 (citing *Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970)). This method involves considering several factors to determine the royalty the parties would have agreed on. *Id.* at 1324-36. "The hypothetical negotiation also assumes that the asserted patent claims are valid and infringed." *Id.* at 1325.

23. The Federal Circuit "has sanctioned the use of the *Georgia–Pacific* factors to frame the reasonable royalty inquiry." *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed. Cir. 2011). The *Georgia-Pacific* factors include:

> 1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
>
> 2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
>
> 3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
>
> 4. The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
>
> 5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.

6. The effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.

7. The duration of the patent and the term of the license.

8. The established profitability of the product made under the patent; its commercial success; and its current popularity.

9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.

10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.

14. The opinion testimony of qualified experts.

15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee— who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention— would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

See Georgia-Pac. Corp., 318 F. Supp. at 1120.

C. Willful Infringement

Whether Counter-Defendants willfully infringe the asserted claims of the Wilton Patents.

Legal Authority:

24. "[T]he concept of 'willfulness' requires a jury to find no more than deliberate or intentional infringement." *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1378 (Fed. Cir. 2020). The willfulness inquiry is separate from the enhanced damages inquiry. *See SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1329-30 (Fed. Cir. 2021) ("To eliminate the confusion created by our reference to the language 'wanton, malicious, and bad-faith' in *Halo*, we clarify that it was not our intent to create a heightened requirement for willful infringement. Indeed, that sentence from *Halo* refers to 'conduct warranting enhanced damages,' not conduct warranting a finding of willfulness." (citing *Halo Elecs., Inc. v. Pulse Elecs, Inc.*, 579 U.S. 93, 103 (2016))).

25. "Proof of an objectively reasonable litigation-inspired defense to infringement is no longer a defense to willful infringement." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016).

26. Several factors can be considered in determining willfulness, for example: "(1) Whether or not [the defendant] intentionally copied a product . . . covered by [the patent-in-suit]; (2) Whether or not [the defendant] reasonably believed it did not infringe or that the patent was invalid; (3) Whether or not [the defendant] made a good-faith effort to avoid infringing [the patent-in-suit], for example, whether [the defendant] attempted to design around [the patent-in-suit]; and (4) Whether or not [the defendant] tried to cover up its infringement." *Eko*, 946 F.3d at 1377-78; *see also Arctic Cat Inc. v. Bombardier Recreational Prods., Inc.*, 876 F.3d 1350, 1371 (Fed. Cir. 2017) (finding of willful infringement supported by facts that the defendant "knew about the patents before they issued, conducted only a cursory analysis of the patents, waited years before seeking advice of qualified and competent counsel, and unsuccessfully tried to buy the asserted patents through a third party").

D. Enhanced Damages

Whether Counter-Plaintiffs are entitled to enhanced damages under 35 U.S.C. § 284.

Legal Authority:

27. 35 U.S.C. § 284 gives the Court discretion to "increase the damages up to three times the amount found or assessed" by the jury. *Halo Elecs.*, 579 U.S. at 97 (cleaned up). "The sort of conduct warranting enhanced damages has been variously described in [] cases as willful, wanton, malicious, bad faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Id.* at 103-04.

28. "[T]he *Halo* Court explained that the [plaintiff] need simply prove willfulness by a preponderance of the evidence, and that an independent showing of objective recklessness was not required." *Varian Med. Sys., Inc. v. Elekta AB*, No. 15-0871-LPS, 2016 WL 3748772, at *7 (D. Del. July 12, 2016) (quoting *Halo Elecs.*, 579 U.S. at 105-06). Rather, "[a] patent infringer's subjective willfulness, whether intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." *Halo Elecs.*, 579 U.S. at 94. "[T]he focus should be on whether the [plaintiff] has shown that this is an 'egregious case[] of misconduct beyond typical infringement.'" *Varian Med. Sys.*, 2016 WL 3748772, at *7 (quoting *Halo Elecs.*, 579 U.S. at 110).

29. A defendant "cannot insulate itself from liability for enhanced damages by creating an . . . invalidity defense for trial after engaging in the culpable conduct of copying, or 'plundering' [the plaintiff's] patented technology prior to litigation." *WBIP*, 829 F.3d at 1340-41.

E. Exceptional Case and Attorneys' Fees

Whether this case is an exceptional case under 35 U.S.C. § 285, and whether Counter-Plaintiffs should be awarded attorneys' fees under § 285, Fed. R. Civ. P. 54(d), and/or the Court's inherent powers.

Legal Authority:

30. Under 35 U.S.C. § 285, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party."

31. According to the Supreme Court, "an 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014). "District courts may determine whether a case is 'exceptional' in the case-by-case exercise of their discretion, considering the totality of the circumstances." *Id.*

32. "[W]hether to award attorney fees" requires the court to "weigh factors such as degree of culpability, closeness of the questions, and litigation behavior[,]" also requiring a "context-specific" analysis. *Nilssen v. Osram Sylvania, Inc.*, 528 F.3d 1352, 1357-59 (Fed. Cir. 2008). District courts may consider "frivolousness," "objective unreasonableness (both in the factual and legal components of the case)[,]" need for "compensation and deterrence[,]" and "bad faith, vexatious[], [or] wanton[]" litigation conduct. *Rothschild Connected Devices Innovations, LLC v. Guardian Prot. Servs., Inc.*, 858 F.3d 1383, 1387 (Fed. Cir. 2017).

F. Pre-Judgment Interest

Whether Counter-Plaintiffs are entitled to pre-judgment interest under 35 U.S.C. § 284, and if so, at what rate and whether it should be compounded.

Legal Authority:

33. In addition, upon a finding of infringement, prejudgment interest "should ordinarily be awarded where necessary to afford the plaintiff full compensation for the infringement." *Schwendimann v. Arkwright Advanced Coating, Inc.*, 959 F.3d 1065, 1076 (Fed. Cir. 2020) (quoting *Gen. Motors*, 461 U.S. at 654). "Awarding prejudgment interest is the rule, not the

exception." *Id.* (quoting *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1574 (Fed. Cir. 1996)). The rate of prejudgment interest and whether it should be compounded or uncompounded are matters within the district court's discretion. *Nickson Indus. v. Rol Mfg.*, 847 F.2d 795, 800 (Fed. Cir. 1988); *Bio-Rad Laby's, Inc. v. Nicolet Instrument Corp.*, 807 F.2d 964, 969 (Fed. Cir. 1986).

G. Costs

Whether Counter-Plaintiffs are entitled to costs under 35 U.S.C. § 284, 28 U.S.C. § 1920, and/or Fed. R. Civ. P. 54(d), and if so, the amount.

Legal Authority:

34. The process of deciding whether to award costs in a patent trial is no different than that employed in any other type of trial. *Manildra Milling Corp. v. Ogilvie Mills, Inc.*, 76 F.3d 1178, 1183 (Fed. Cir. 1996). Pursuant to Federal Rule of Civil Procedure 54(d)(1), costs must be awarded to the prevailing party as a matter of course, unless the court directs otherwise. *Id.* By statute, courts have discretion to award costs for: (1) clerk and marshal fees; (2) court reporter fees; (3) printing and witness fees; (4) copying fees; (5) docket fees; and (6) compensation for court-appointed experts, interpreters, and special interpretation services. 28 U.S.C. § 1920; *see also* 28 U.S.C. § 1821; D. Del. LR 54.1.

III. BREACH OF CONTRACT

A. Breach

Whether NS Japan materially breached the Mutual Confidentiality Agreement ("MCA").

Legal Authority:

35. Confidentiality agreements such as the MCA are intended to preserve the confidentiality of the parties' business discussions during confidential negotiations. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1375 n.1 (Fed. Cir. 2007). Indeed, the Federal Circuit recognized that the purpose of such agreements is "[t]o avoid the risk of a declaratory

judgment action." *Id.* Courts give effect to such provisions in this context: "[P]arties wishing to avoid the risk of costly litigation, such as a declaratory judgment action in a noninfringement suit, should negotiate and agree to a suitable confidentiality agreement to prevent disclosure of communications received during settlement negotiations." *Osteotech, Inc. v. Regeneration Techs., Inc.*, No. 3:06-cv-04249-FLW, 2008 WL 4449564, at *4 (D.N.J. Sept. 25, 2008).

36. Under Delaware law, a party's disclosure of confidential information in violation of a contract is a "material breach" when the confidentiality provisions are "central to the parties' agreement." *eCommerce Indus., Inc. v. MWA Intel., Inc.*, No. CV 7471-VCP, 2013 WL 5621678, at *19 (Del. Ch. Sept. 30, 2013); *see also Red Cat Holdings, Inc. v. Autonodyne LLC*, No. 2022-0878-NAC, 2024 WL 342515, at *8 (Del. Ch. Jan. 30, 2024) (holding a breach of a confidentiality clause was material when "[t]he parties expressly bargained for a prohibition on the disclosure of Confidential Information."). Additionally, a breaching party's failure to attempt to cure a breach and lack of good faith also indicate that a breach was material. *eCommerce Indus.*, 2013 WL 5621678, at *19.

B. Damages

Whether Sarepta is entitled to damages to compensate it for NS Japan's material breach of the MCA, and if so, the amount.

Legal Authority:

37. A claim for breach of contract requires that the breach of the contract was the proximate cause of damages. *Johnson v. Gov't Emps. Ins. Co.*, No. CV 06-408-RGA, 2014 WL 2708300, at *1 (D. Del. June 16, 2014), *aff'd sub nom. Johnson v. GEICO Cas. Co.*, 672 F. App'x 150 (3d Cir. 2016) (citing *VLIW Tech., LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 612 (Del. 2003).

38. Delaware courts recognize that legal fees and increased litigation costs caused by an alleged breach can form the basis of a claim for damages. *See, e.g., Henkel Corp. v. Innovative Brands Holdings, LLC*, No. CIV.A. 3663-VCN, 2013 WL 396245, at *2 (Del. Ch. Jan. 31, 2013) (legal fees incurred as a result of having to take additional actions because of the alleged breach form the basis for damages); *Universal Enter. Grp., L.P. v. Duncan Petroleum Corp.*, No. CV 4948-VCL, 2013 WL 3353743, at *20 (Del. Ch. July 1, 2013) (awarding legal fees incurred as a result of a breach of contract); *Country Life Homes, LLC v. Gellert Scali Busenkell & Brown, LLC*, 259 A.3d 55, 60 (Del. 2021) ("increased litigation expenses" can form the basis for damages).

39. Under Delaware law, "a court can vindicate a breach of contract that does not give rise to monetary damages through an award of nominal damages." *Garfield on behalf of ODP Corp. v. Allen*, 277 A.3d 296, 328 (Del. Ch. 2022). "Thus, a plaintiff need not plead monetary damages to sustain a breach of contract claim." *Id.*

IV. INVALIDITY OF THE NS PATENTS[2]

A. Person of Ordinary Skill in the Art

What is the appropriate definition of a person of ordinary skill in the art ("POSA") relating to U.S. Patent Nos. 10,385,092 ("the '092 Patent"); 10,407,461 ("the '461 Patent"); 10,487,106 ("the '106 Patent"); 10,647,741 ("the '741 Patent"); 10,662,217 ("the '217 Patent"); and 10,683,322 ("the '322 Patent").

Legal Authority:

40. A POSA is "a hypothetical person who is presumed to be aware of all the pertinent prior art." *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962-63 (Fed. Cir. 1986). "Factors that may be considered in determining level of ordinary skill in the art include:

[2] The NS Patents refer to U.S. Patent Nos. 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322.

(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Id.*; *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). These factors are not exhaustive, and one or more of these factors may predominate. *Daiichi Sankyo*, 501 F.3d at 1256; *Custom Accessories*, 807 F.2d at 962-63.

41. "The actual inventor's skill is not determinative." *Custom Accessories*, 807 F.2d at 963. But the inventor's educational level can be considered in determining the level of skill in the art. *See Daiichi Sankyo*, 501 F.3d at 1257 (determining the level of skill in the art based on, *inter alia*, the inventors' educational and professional background and the observation that "others working in the same field as the inventors . . . were of the same skill level").

B. Anticipation Under 35 U.S.C. § 102

Whether Sarepta has proven by clear and convincing evidence that each of claims 1-3 of the '092 Patent, claims 1 and 2 of the '461 Patent, claims 1 and 2 of the '106 Patent, claims 1-12 of the '741 Patent, and claims 1-4 of the '217 Patent is invalid as anticipated under 35 U.S.C. § 102.

Legal Authority:

42. Under 35 U.S.C. § 102, a patent claim is invalid if "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or . . . (e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2)

a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language . . . ."

43. Anticipation is a question of fact. *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020). The patent challenger bears the burden of proving anticipation by clear and convincing evidence. *See Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1374 (Fed. Cir. 2005).

44. To anticipate, "the reference must disclose each and every element of the claimed invention." *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). "It is well settled that prior art under [35 U.S.C. § 102] must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985).

45. Thus, "the reference need not satisfy an *ipsissimis verbis* test." *Gleave*, 560 F.3d at 1334. Rather, "[i]n an anticipation analysis, the dispositive question is whether a skilled artisan would 'reasonably understand or infer' from a prior art reference that every claim limitation is disclosed in that single reference." *Acoustic Tech.*, 949 F.3d at 1373 (citing *Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1192 (Fed. Cir. 2003)); *see also Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1340 (Fed. Cir. 2020) ("Anticipation is established when 'one of skill in the art would reasonably understood or infer from the prior art reference's teaching that every claim limitation was disclosed in that single reference.'") (quoting

CRFD Rsch., Inc. v. Matal, 876 F.3d 1330, 1338 (Fed. Cir. 2017)); *Arthrocare*, 406 F.3d at 1373-74 ("even if a piece of prior art does not expressly disclose a limitation, it anticipates if a person of ordinary skill in the art would understand the prior art to disclose the limitation and could combine the prior art description with his own knowledge to make the claimed invention") (citing *Helifix Ltd. v. Blok–Lok, Ltd.*, 208 F.3d 1339, 1347 (Fed. Cir. 2000)).

46. While the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus, "[t]his distinction collapses when the class of compounds that falls within the genus is so limited that a person of ordinary skill in the art can at once envisage each member of this limited class." *Gleave*, 560 F.3d at 1337-38 (citation omitted). "In that limited circumstance, a reference describing the genus anticipates every species within the genus." *Id.*; *see also In re Petering*, 301 F.2d 676, 681-82 (C.C.P.A. 1962) (finding anticipation when "one skilled in this art would, on reading [the prior art], at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class"); *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381-83 (Fed. Cir. 2015); *Ineos USA v. Berry Plastics Corp.*, 783 F.3d 865, 871-72 (Fed. Cir. 2015).

47. "The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102 . . . differs from the enablement standard under section 112." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005). For instance, "[a]n anticipatory reference need only enable subject matter that falls within the scope of the claims at issue, nothing more." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003). Further, "[a]nticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure." *Id.* at

1380. "Proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation." *Rasmusson*, 413 F.3d at 1326.

C. Obviousness Under 35 U.S.C. § 103

Whether Sarepta has proven by clear and convincing evidence that each of claims 1-3 of the '092 Patent, claims 1 and 2 of the '461 Patent, claims 1 and 2 of the '106 Patent, claims 1-12 of the '741 Patent, claims 1-4 of the '217 Patent, and claims 1-4 and 6-9 of the '322 Patent is invalid as obvious under 35 U.S.C. § 103.

Legal Authority:

48. Under 35 U.S.C. § 103, a patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

49. Obviousness is a question of law based on underlying findings of fact. *Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1327 (Fed. Cir. 2009). The patent challenger bears the burden of proving the factual elements of obviousness by clear and convincing evidence. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007).

50. The obviousness analysis is an objective one from the perspective of a POSA. *See KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007). The analysis involves factual inquiries into: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) objective indicia of nonobviousness. *Id.* (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)). "While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls." *Id.*

51. "Nonobviousness cannot be established by attacking references individually." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Each reference "must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *Id.* "[T]he mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 229-30 (1976); *see also Scanner Tech. Corp. v. ICOS Vision Sys. Corp*., 528 F.3d 1365, 1381-82 (Fed. Cir. 2008) ("the relatively small logical gap between the prior art and the claim in this case is closed by a person of ordinary skill in the art pursuing known options within his or her technical grasp").

52. "[A] party seeking to invalidate a patent as obvious must demonstrate by clear and convincing evidence that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *In re Cyclobenzaprine Hydrochloride Extended-Related Capsule Pat. Litig.*, 676 F.3d 1063, 1068-69 (Fed. Cir. 2012).

53. "A claim can be obvious even where all of the claimed features are not found in specific prior art references, where 'there is a showing of a suggestion or motivation to modify the teachings of the prior art to the claimed invention.'" *Ormco Corp. v. Align Tech., Inc*., 463 F.3d 1299, 1307 (Fed. Cir. 2006) (quoting *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000)).

54. A motivation to combine the teaching of the prior art "does not have to be found explicitly in the prior art references sought to be combined." *Pfizer,* 480 F.3d at 1362. Rather, it "may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *Id.*; *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022) ("This motivation to combine may be found explicitly

or implicitly in market forces; design incentives; the interrelated teachings of multiple patents; any need or problem known in the field of endeavor at the time of invention and addressed by the patent; and the background knowledge, creativity, and common sense of the person of ordinary skill.").

55. "Obviousness does not require that the motivation be the *best* option, only that it be a *suitable* option from which the prior art did not teach away." *Bayer Pharma AG v. Watson Laby's, Inc.*, 874 F.3d 1316, 1328 (Fed. Cir. 2017) (emphases in original).

56. "Obviousness does not require absolute predictability of success." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). "For obviousness under § 103, all that is required is a reasonable expectation of success." *Id.* at 904. "[T]here is no requirement that a teaching in the prior art be scientifically tested, or even guarantee success, before providing a reason to combine." *Duramed Pharms. Inc. v. Watson Laby's. Inc.*, 413 F. App'x 289, 294 (Fed. Cir. 2011) (internal citation omitted). "Rather, it is sufficient that one of ordinary skill in the art would perceive from the prior art a reasonable likelihood of success." *Id.*

57. "[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer*, 480 F.3d at 1364. Likewise, "lack of certainty does not preclude a conclusion of obviousness." *Warner Chilcott Co., LLC v. Teva Pharms. USA, Inc.*, 594 F. App'x 630, 636 (Fed. Cir. 2014); *see also Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014) ("Conclusive proof of efficacy is not necessary to show obviousness.").

58. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 421. "If this leads

to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.*

59. A POSA is a person of ordinary creativity, "not an automaton." *Id.* at 421. Thus, the obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418.

60. "[S]tructural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case." *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc); *see also In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (holding that a person of skill in the art would have expected amitriptyline to resemble imipramine in the alleviation of depression in humans because of the drugs' close structural similarity and similar use); *In re Payne*, 606 F.2d 303, 314 (C.C.P.A. 1979) ("Because of the close structural similarity between the claimed compounds at issue here and the compounds [in the prior art], and because those prior art compounds possess pesticidal activity, we conclude that the required motivation is present here." (citing *In re Wood*, 582 F.2d 638, 641 (C.C.P.A. 1978)); *In re Rosselet*, 347 F.2d 847, 850 (C.C.P.A. 1965) ("[A]ppellants have failed to present adequate evidence to overcome a prima facie showing of obviousness by reason of the admitted 'gross structural similarities' of the art compounds, coupled with the fact those compounds are shown to have utility in the same area of pharmacological activity.").

61. Objective evidence of nonobviousness, which sometimes referred to as secondary considerations, must be considered as part of obviousness analysis. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013); *see Graham*, 383 U.S. at 17-18. But "the objective evidence of nonobviousness simply cannot overcome . . . a strong prima facie case of obviousness." *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008).

62. "Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention." *Power Integrations*, 711 F.3d at 1368.

63. "For objective indicia evidence to be accorded substantial weight, . . . a nexus must exist between the evidence and the merits of the claimed invention." *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1330 (Fed. Cir. 2017) (citation omitted). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention." *Id.* (emphasis in original) (quoting *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011)). "The patentee bears the burden of showing that a nexus exists between the claimed features of the invention and the objective evidence offered to show non-obviousness." *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1360 (Fed. Cir. 1999).

64. "Unexpected results that are probative of nonobviousness are those that are different in kind and not merely in degree from the results of the prior art." *Galderma Laby's, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013); *see also KSR*, 550 U.S. at 416 ("The

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). "To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc*., 752 F.3d 967, 977 (Fed. Cir. 2014).

65. "Independently made, simultaneous inventions, made within a comparatively short space of time are persuasive evidence that the claimed [subject matter] was the product only of ordinary mechanical or engineering skill." *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l., LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010); *Ecolochem, Inc. v. S. Cal. Edison Co*., 227 F.3d 1361, 1379 (Fed. Cir. 2000) ("The fact of near-simultaneous invention, though not determinative of statutory obviousness, is strong evidence of what constitutes the level of ordinary skill in the art.") (citation omitted); *Regents of Univ. Cal. v. Broad Inst., Inc*., 903 F.3d 1286, 1298 (Fed. Cir. 2018) ("Simultaneous invention may serve as evidence of obviousness when considered in light of all of the circumstances.").

66. Whether inventions by others are simultaneous is measured from the patentee's alleged time of invention. *See Trs. of Columbia Univ. in City of New York v. Illumina, Inc.*, 620 F.App'x 916, 930 (Fed. Cir. 2015) ("simultaneous invention is relevant when it occurs within a short space of time from the date of invention"); *see also Geo. M. Martin*, 618 F.3d at 1305 (evaluating simultaneousness based on the date that the inventors "reduced their claimed invention to practice"); *Endo Pharms. Inc. v. Actavis Inc.*, No. 14-1381-RGA, 2017 WL 3731001, at *12 (D. Del. Aug. 30, 2017), *aff'd*, 922 F.3d 1365 (Fed. Cir. 2019) (evaluating simultaneousness based on the "invention date").

D. Lack of Written Description Under 35 U.S.C. § 112, First Paragraph

Whether Sarepta has proven by clear and convincing evidence that each of claims 1-3 of the '092 Patent, claims 1 and 2 of the '461 Patent, claims 1 and 2 of the '106 Patent, claims 1-12 of the '741 Patent, claims 1-4 of the '217 Patent, and claims 1-4 and 6-9 of the '322 Patent is invalid for lack of written description under 35 U.S.C. § 112, first paragraph.

Legal Authority:

67. Under 35 U.S.C. § 112, first paragraph, "[t]he specification shall contain a written description of the invention." This requirement is often referred to as the written description requirement, which is a separate requirement from the enablement requirement. *See Ariad Pharms. Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

68. Written description is a question of fact. *Id*. The patent challenger bears the burden of proving by clear and convincing evidence that the written description requirement has not been satisfied. *Id*. at 1354.

69. To satisfy the written description requirement, the patent specification "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Id*. at 1351 (citation omitted). "In other words, the test for sufficiency is whether the disclosure of the [specification] relied upon reasonably conveys to those skill in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.*

70. "[T]he hallmark of written description is disclosure. . . . [T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id*.

71. "[W]hile the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement." *Id*. at 1352 (internal citation omitted).

V. UNENFORCEABILITY OF THE NS PATENTS

Whether Sarepta has proven by clear and convincing evidence that each of the NS Patents is unenforceable due to inequitable conduct.

Legal Authority:

72. "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co*., 649 F.3d 1276, 1285 (Fed. Cir. 2011) (en banc). "To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO." *Id*. at 1287. "The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence." *Id.*

73. "[T]he materiality required to establish inequitable conduct is but-for materiality." *Id*. at 1291. In assessing the materiality of withheld information, "the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed" information. *Id*. "In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction" in accordance with the PTO's examination standards. *Id.*; *Aventis Pharma S.A. v. Hospira, Inc*., 675 F.3d 1324, 1334 (Fed. Cir. 2012) ("[T]he standard for establishing but-for materiality in the inequitable conduct context only requires a preponderance of the evidence") (citation omitted).

74. To be but-for material, a withheld reference should not be cumulative to the information submitted to the PTO. *Regeneron Pharms. Inc. v. Merus N.V*., 864 F.3d 1343, 1350

(Fed. Cir. 2017). "A reference is cumulative when it teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO." *Id.* (citation omitted).

75. "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." *Therasense*, 649 F.3d at 1290. The intent required to establish inequitable conduct is "the specific intent to deceive the PTO." *Id.* "A finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement." *Id.* "[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Id.*

76. In some cases, the specific intent to deceive has been inferred from "a pattern of intentional conduct designed to deceive the attorneys and patent office." *See, e.g.*, *Frank's Casing Crew & Rental Tools, Inc. v. PMR Techs., Ltd.*, 292 F.3d 1363, 1376 (Fed. Cir. 2002); *Finjan, Inc. v. Juniper Network, Inc.*, No. C 17-05659 WHA, 2018 WL 4181905, at *7 (N.D. Cal. Aug. 31, 2018) ("[W]e see a pattern and practice of bringing to the attention to the PTO critical information only after the PTO examiner or industry itself has exposed the original priority date as ineffective to support a valid invention").

77. "[A] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990); *see also Truth Hardware Corp. v. Ashland Prods., Inc.*, No. 02-1541-GMS, 2003 WL 22005839, at *1 (D. Del. Aug. 19, 2003) ("It is well-settled that a patentee's inequitable conduct renders unenforceable all patent claims having 'an immediate and necessary relation' to that conduct, regardless of whether the

claims are contained in a single patent or a series of related patents."). For example, "a patent that issues from a divisional or continuation application may be held unenforceable where (i) there is inequitable conduct with respect to the prosecution of an earlier related application in the chain leading to the challenged patent and (ii) the inequitable conduct relates to the asserted claims of that [divisional or continuation] patent. Were this not the rule, a party committing inequitable conduct could avoid the consequences of that conduct through a scheme of divisional and continuation applications. The law does not countenance such a manipulation of the patent process." *Id*. (citing *Semiconductor Energy Lab'y Co., Ltd. v. Samsung Elecs. Co., Ltd*., 24 F. Supp. 2d 537, 543-44 (E.D. Va. 1998)).